3-vinyl-3-cephem-4-carboxylic acid (syn isomer), useful as an antimicrobial agent. The compound in its amorphous form is known to the prior art, namely in Takaya 4,559,334. The disadvantage of such amorphous product is that it is bulky, not sufficiently pure, unstable and insufficient in its filtration rate, therefore not being suitable for a pharmaceutical product and not being easy to handle in pharmaceutical preparations. By virtue of the present invention said compound has been provided in a novel crystalline form, having distinguishing peaks at the diffraction angles specified in principal Claim 1. The crystalline form of the present invention has improved color and potency as compared to the amorphous product of the Takaya patent, said advantageous characteristics having been verified at pages 5-6 of the present specification.

Reconsideration is requested of the rejection of the claims under 35 USC 103 as unpatentable over Takaya. Applicants urge that the position of the Examiner does not follow the precedent of conventional patent practice, and furthermore that Takaya contains no suggestion whatsoever of the presently claimed subject matter.

At most, Takaya discloses that the compounds in amorphous, powdery form are known to the prior art, as admitted by the present Applicants at page 1 of this specification. The Examiner errs in his position that "different forms of the same compound are presumptively non-patentable", since the Examiner does not take into consideration the fact that the present compounds are crystalline, are characterized by peaks at the specified diffraction angles recited in Claim 1, and the crystalline form of the compound is unknown, unobvious, and productive of unexpected advantageous results, as verified in this specification.

The citation of the Merck Index is not seen to bolster the Examiner's position, since, at most, page 268 cited by the Examiner merely states that Cefadroxil (which is quite remote from the presently claimed compounds) is known to exist as white crystals. In what manner would such disclosure by the Merck Index suggest to one skilled in the art that the crystalline form of the presently claimed compounds would yield superior color and potency as compared to the amorphous form of the prior art.

The Examiner takes the further position that Ex parte Hartop, 139 USPQ 525, supports his positions.

Applicants urge that the doctrine of ex parte Hartop is not pertinent to the present situation, nor is it persuasive of unpatentability of the present claims. Ex parte Hartop states "the products are merely different forms of known compounds and, not withstanding that some desirable results are obtained therefrom, since the products have the same utility as the prior art compounds, they have been held unpatentable". But such statement in Ex parte Hartop is not pertinent here where the crystalline product is being claimed, for the reason that the utility of said crystalline product is not the same as the utility of the amorphous product of Takaya. Granted they are both antimicrobial agents, but the "utility" is distinguishable on the ground that the amorphous products cannot be successfully used for preparing commercial pharmaceutical compositions since such amorphous products are undesirably unstable, while the crystalline product of the present invention is sufficiently stable for utility in successful commercial pharmaceutical compositions. Applicants urge that the utility of the crystalline product of the present invention is different from the utility of the amorphous product of Takaya, from the point of view as

to whether the product can be used as a stable component of a successful commercial product. This difference in "success" is highly significant, since medicines are not realistically "useful" if they cannot be brought to market in a stable state, and be of benefit to patients in need of such medicines. Applicants therefor urge that the present invention is patentable over Takaya based on the specific logic applied in Ex parte Hartop, namely that if a prior art product cannot be used for the specific purpose asserted for the presently claimed product, as in the instant situation, then invention can be held to be present.

While it is firmly believed that the data at pages 5 and 6 of this specification adequately establishes the beneficial and unobvious results of the presently claimed crystalline form, the data evidencing improved stability, color and potency, nevertheless to further demonstrate the advantages hereof, there is appended to this response a set of declarations from Takaya and Okamoto. The samples prepared in the Takaya declaration are identical to those at page 5 of the specification, namely Samples 1 and 2 representing Takaya while Sample A represents the present

application. In the Okamoto declaration, the stability of each sample is evaluated in terms of the falling off of potency after one month. It will noted that the samples representing Takaya fall in potency from 100 percent to 68.4 and 26.4 percent respectively, while the potency of the sample representing the present invention has a minor variation from 100 percent to 99.3 percent. Clearly, Sample A demonstrates a stability far greater than the amorphous compounds of the prior art, and it is believed that this comparative data, coupled with the comparative data of the specification as originally filed, clearly overcomes the Examiner's positions.

Finally, the Examiner takes a further erroneous position in stating that "preparing the crystalline form of a known compound follows the teachings of the art", since the method of preparation of the crystalline form of the presently claimed compounds is not considered the heart of the present invention. The crystalline form of the compound represents the inventive concept hereof, and it is clear that Takaya does not anticipate or suggest said crystalline form. In any event, it might further be noted that the preparation procedure of Claims 6-8 is not disclosed in

Takaya, nor has the Examiner stated that the preparation procedure of said claims is known to the art.

In summary, Applicants have provided a novel crystalline form of a known compound, which crystalline form is unknown, unobvious, and productive of unexpected advantageous results. Such novel crystalline form is entitled to patentability.

Early Notice of Allowance is respectfully requested.

Respectfully submitted,

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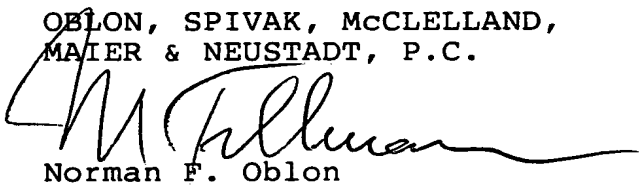

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